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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,442	03/22/2001	Sean Ekins	PC10607AMEB	4594

7590 06/17/2003
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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,442

Applicant(s)

EKINS ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

Applicant's election of species of "an enzyme" in Paper No. 4, filed 4/7/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

An action on the merits of claims 1-6 and 9-10, as they read on enzymes, follows.

Drawings

The drawings are objected to as set forth on the attached Form PTO 948. A proposed drawing correction or corrected drawings are required in reply to this Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate

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paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the specification or the prior art teach how to use an equation to predict the IC_{50} of a compound at a single concentration wherein a percent response (e.g. inhibition) is not measured at that concentration. Pages 2-4 of the specification disclose that the inventive method is directed to determination of IC_{50} values of compounds by screening at a single

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concentration, thus implying that an assay (screen) is actually performed at the single concentration. The specification does not disclose any working examples for actually determining an IC_{50} of a "remaining or future" (unknown?) compound at a single concentration using an equation as determined by claimed step (d). The specification does not specifically provide guidance for predicting an IC_{50} of a compound using an equation obtained through the claimed method steps. The state of the prior art is such that one skilled in the art would generally expect to enter data, usually obtained from experiments, which corresponds to a variable, into an equation to predict a property of a compound. The level of skill in the art is acknowledged to be high; however, without a step of actually obtaining a percent response of an unknown compound for entry into the claimed equation, one skilled in the art would not reasonably expect success in predicting the IC_{50} of a compound using only the equation calculated by the claimed method steps. For these reasons, it would require undue experimentation by one skilled in the art to determine an IC_{50} of a compound using the claimed method steps. For all of the reasons set forth above, the claims are not enabled.

Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

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Claims 9-10 limit the claimed method to one wherein a biological assay relates to affinity of a target protein wherein modulation of activity is therapeutically desired, or for a nontherapeutic protein wherein modulation of activity is undesirable. The specification discloses, on page 14, that drug-drug interaction are an important factor in whether a new chemical entity "will survive through to the development stage." The specification makes no other disclosure with regard to drugs (therapeutic compounds?), target proteins which may or may not be therapeutic, biological assays relating to such, or any activity thereof wherein modulation is or is not desired. As the specification provides no description or support for the limitations of claims 9-10, claims 9-10 are rejected for lack of written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a step (c) of determining an IC_{50} or EC_{50} for "these initial compounds". Step (d) of claim 1 also recites a step of "using" data from "these initial compounds." It is not clear if the antecedent basis for "these initial compounds" is the "initial collection of at least 10 compounds" only, of step (a), or is the "initial collection....,

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and at least one commercially available compound" also recited in step (a), therefore the claim is indefinite.

Claim 1, step (a) recites the phrase "to be used as a positive control" with regard to a "commercially available compound". It is unclear what limitation applicant intends by this phrase. If this phrase is intended to limit the commercially available compound, then it is unclear what structural or functional limitation is intended of the compound itself. If applicant intends the phrase to limit the claimed method, then it is unclear what method step, or limitation thereof, applicant intends, as no step of comparison to a positive control is recited anywhere in the claims. As the limitation intended by use of this phrase is unclear, the claim is indefinite.

Claim 1, step (d) recites "using" data from compounds to fit a mathematical relationship between IC_{50} or EC_{50} values and percent inhibition values at a single concentration. It is unclear if applicant intends to "use" the data from each of the compounds, individually, to combine the data from the compounds before "use" in the mathematical fitting, or to use some subset of data, therefore the claim is indefinite.

Claim 1, step (e) recites "all remaining and future test compounds." As no smaller set, or subset, or subtractive set of data is recited in the claim, it is unclear what data applicant intends by "all remaining...compounds", therefore claim 1 is indefinite. In addition, neither the specification nor claims define what set of compounds is encompassed by "all...future test compounds". As the metes and bounds intended by applicant for "all... future test compounds" is unclear, claim 1 is further indefinite.

Although the genus of "future test compounds" is not disclosed by the specification, the

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claim is not rejected herein for lack of written description of this limitation, but merely for indefiniteness, as it is unclear what applicant intends by this phrase.

Conclusion

Claims 1-6 and 9-10 are rejected; claims 7-8 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran

mam
June 16, 2003